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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,043	04/12/2004	Bartie Tan	BT-001	4102
38051	7590	09/07/2005	EXAMINER	
KIRK HAHN 14431 HOLT AVE SANTA ANA, CA 92705			MCCORMICK EWOLDT, SUSAN BETH	
		ART UNIT	PAPER NUMBER	
		1655		

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/823,043	TAN ET AL.
	Examiner S. B. McCormick-Ewoldt	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 July 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 18-24 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) 3 and 17 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 November 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>July 14, 2004</u> & <u>April 4, 2005</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1655

DETAILED ACTION

Status of Application

The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1655.

Election/Restrictions

Applicant's election without traverse of Group I and the species elected, palm extract, in the reply filed on July 21, 2005 is acknowledged.

Claims 18-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 21, 2005.

Claims Pending

Claims 1-17 will be examined on the merits and solely in regards to the elected species. Claims 18-24 are withdrawn.

Claim Objections

Claims 3 and 17 are objected to because of the following informalities: no period at the end of the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, 5, 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claim 2 the recitation “natural extract” is indefinite because it is not clear what is encompassed by this recitation. Clarification is needed.

In claim 3 the recitation “low levels” is indefinite because it is not clear what is encompassed by this recitation. Clarification is needed.

In claim 6, the recitation “appropriate spectrum” is not clearly defined in the specification. Clarification is needed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Tan (US 6,350,453).

Tan (US 6,350,453) teaches that *Bixa orellana* (i.e. annatto) contains tocotrienols and are known to have beneficial effects against hypcholesterolemia, reduce lipoprotein plasma levels and be useful in the treatment of cardiovascular disease (column 1, lines 10-47). Tan *et al.* also disclose a method to separate tocopherols and tocotrienols so essentially no tocopherols are present (column 2, lines 4-6, 18-20, 45-49). Thus Tan anticipates the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 11-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Levy *et al.* (US 2003/0104090).

Levy *et al.* (US 2003/0104090) teach that annatto extracts (i.e. *Bixa orellana*) contains vitamin E tocotrienol ([0002]). Levy *et al.* teach that therapeutic health benefits also include improving symptoms of diabetes, inhibiting atherosclerosis and/heart disease, lowering LDL cholesterol and protecting neuron cells from being killed due to stroke, inflammation or neurodegenerative disease ([0016] and [0034]). Thus, Levy *et al.* anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan (US 6,350,453), Wright *et al.* (US 5,217,992) and Levy *et al.* (US 2003/0104090).

Tan (US 6,350,453) disclose that *Bixa orellana* (i.e. annatto) contains tocotrienols and are known to have beneficial effects against hypcholesterolemia, reduce lipoprotein plasma levels and be useful in the treatment of cardiovascular disease (column 1, lines 10-47). Tan *et al.* also disclose a method to separate tocopherols and tocotrienols so essentially no tocopherols are

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present (column 2, lines 4-6, 18-20, 45-49). Tan does not disclose specifically using alpha-T1, delta-T3 or gamma-T3

Wright *et al.* (US 5,217,992) disclose delta and gamma tocotrienols in palm oil act as inhibitors of lowering serum total cholesterol and LDL-cholesterol in humans (column 4, lines 23-33).

Levy *et al.* (US 2003/0104090) discloses that annatto extracts (i.e. *Bixa orellana*) contains vitamin E tocotrienol ([0002]). Levy *et al.* disclose that therapeutic health benefits also include improving symptoms of diabetes, inhibiting atherosclerosis and/heart disease, lowering LDL cholesterol and protecting neuron cells from being killed due to stroke, inflammation or neurodegenerative disease ([0016] and [0034]).

The references taken together teach that annatto extract and palm oil are used in a composition for decreasing blood levels of triglycerides and treats maladies of the central nervous system. Thus, a person of ordinary skill in the art would reasonably expect that annatto extract and palm oil would be successfully used to decrease blood levels of triglycerides and treats maladies of the central nervous system. Based on this reasonable expectation for success, a person of ordinary skill in the art would be motivated to modify the teachings of the references.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions decreasing blood levels of triglycerides and treats maladies of the central nervous system. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80;

440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions for decreasing blood levels of triglycerides and treats maladies of the central nervous system, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions decreasing blood levels of triglycerides and treats maladies of the central nervous system. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Lee
8-31-05
SUSAN COE
PRIMARY EXAMINE: